In re U.S. Patent Application of Jens PETERSEN et al.
Serial No.: 09/938,670 Filing Date: August 27, 2001
Title: POLYACRYLAMIDE HYDROGEL AND ITS USE AS AN ENDOPROSTHESIS

REMARKS

I. Statement

A personal Examiner interview was held on December 8, 2004. During the interview, currently pending independent claim 1 was discussed in view of U.S. Patent No. 4,074,039 to Lim *et al.* (Lim).

The claimed invention of the Application was distinguished from the disclosure of Lim. The Application is directed to a pliable hydrogel that takes the shape of the cavity into which it is administered, e.g., implanted or injected. Lim, however, discloses a hydrogel that is shaped in a mold, which is used as a polymerization vessel, to take the shape of the mold. Lim's shaped hydrogel does not take the shape of the cavity in which it is implanted. See Lim, Col. 2, 11. 7-9, Col. 3, 11. 19-21 and Col. 5, 11. 1-7.

Three properties were discussed that support this distinction. First, the Application claims a hydrogel comprising about 0.5% to 3.5% of polyacrylamide by weight based on the total weight of the hydrogel. Lim, on the other hand, discloses shaped hydrogels containing 60% to 80% solid weight content before washing (for instance, see Examples 6, 1 and 2). Lim discloses washing of his shaped hydrogel, but does not disclose solid weight content of the washed hydrogel. See Example 1. Although, washing reduces the solid weight content, it is known in the art that not more than about 50% of solid weight content would be removed by washing, producing hydrogels with approximately 30% to 40% solid weight content. This is still about ten times greater than the claimed hydrogel of the Application.

Second, the Application claims a hydrogel having a complex viscosity from about 2 to 90 Pas, which provides for a colloidal solution. Lim does not disclose a specific complex viscosity; however, a solid hydrogel that retains its shape should have a complex viscosity that is significantly greater (probably approximately 100 times greater).

Third, the Application claims a molar ratio of acrylamide to methylene bis-acrylamide (i.e., monomer to cross-linking agent) of 150:1 to 1000:1. On the contrary, Lim discloses a generally greater amount of a cross-linker than monomer. See Col. 2, 11. 46-47. Therefore, the hydrogel disclosed in Lim would be denser than the hydrogel of the Application.

The Examiner stated that in view of the stated distinctions, the claimed invention appeared to be patentable over Lim. The Examiner also stated that the obviousness rejection for

claim 47 would be moot. Finally, the Examiner agreed that the amendment to claim 46 (set forth above) would overcome the indefiniteness rejection.

II. Amendment

Reconsideration of rejections in the Application is respectfully requested. Applicants cancelled withdrawn claims 13-40, 42 and 43 without prejudice and to expedite prosecution. Applicants reserve all their rights to pursue protection for the subject matter of all cancelled claims in future patent applications. Upon entry of the foregoing amendment, claims 1, 2, 5, 7-12, and 44-50 will be pending. Claims 1, 2, 5, 7-12 and 44-47 stand rejected. Claim 46 is amended. New claims 48-50 are added.

Applicants respectfully request entry of the above amendment and submit that the amendment does not introduce new matter. Support for the amendment to the claims can be found throughout the specification (considered as a whole) and in the claims as originally as filed. In particular, support for the amendment to claim 46 can be found, *inter alia*, in claim 12 as originally filed and in the specification at page 11, lines 8-12. Support for added claim 48 can be found, *inter alia*, in claim 1 as originally filed and in the specification at page 5, lines 29-31 and page 25, Table 4. Support for added claims 49 and 50 can be found, *inter alia*, in claim 1 as originally filed and in the specification at page 5, lines 29-31 and page 22, Table 2-page 25, Table 4.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

III. Claim Rejections

Claim 46 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the invention. Claims 1, 2, 5, 7-12 and 44-46 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over Lim. Claim 47 stands rejected under 35 U.S.C. § 103(a) as allegedly obvious over Lim in view of U.S. 5,652,274 to Martin (Martin).

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Rejection under 35 U.S.C. § 112.

Claim 46 stands rejected under 35 U.S.C. § 112, second paragraph. Applicants respectfully submit that claim 46 prior to its amendment herein was definite because it readily appraised persons skilled in the art of the metes and bounds of the claimed invention. In the interest of expediting prosecution, Applicants amended this claim. As stated above, the Examiner found during the interview that claim 46 as amended overcomes his concerns and is definite. Therefore, Applicants respectfully request the withdrawal of the rejection of claim 46 under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. § 102(b)/103(a)

Claims 1, 2, 5, 7-12, and 44-46 stand rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over Lim. Claim 47, which depends from claim 1, stands rejected as obvious over Lim in view of Martin.

As previously stated, the patentable distinctions between the claimed invention of the Application and the disclosure of Lim were successfully pointed out during the Examiner interview. The Examiner stated that the claimed invention appeared to be patentable over the prior art, and therefore, both the anticipation rejection under 35 U.S.C. § 102(b) and the obviousness rejection under 35 U.S.C. § 103(a) in view of Lim should be withdrawn.

Claim 47 depends from claim 1 and Martin was cited only for its teaching of a combination of a hydrogel with active substances, including cells. Thus the obviousness rejection under 35 U.S.C. § 103(a) over Lim and Martin should be rendered moot in light of the above, consistent with the Examiner's indication at the interview.

CONCLUSION

For at least the reasons stated above, claims 1, 2, 5, 7-12 and 44-50 are in condition for allowance. Accordingly, Applicants respectfully request that the Application be allowed and passed to issue.

In the event any outstanding issues remain, Applicants would appreciate the courtesy of a telephone call to Applicants' undersigned representative to resolve such issues in an expeditious manner.

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It is believed that no additional fees are due. In the event it is determined by the PTO that there is a discrepancy between the fees due and the amount previously authorized to be deducted from the undersigned's Deposit Account, including any extensions of time fees, the Commissioner is authorized to debit or credit the undersigned's Deposit Account No. 50-0206 accordingly.

Respectfully submitted,

Date: December 13, 2004

By: _____
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